

Appl. No. : 10/072,539
Filed : February 8, 2002

REMARKS

Claims 1-16 were pending in the present application. By way of the present amendment, Applicants have amended Claims 1, 10, and 12-15. Claims 10 and 12-14 were amended to correct their dependency and not for reasons of patentability. Claim 15 was amended to correct its dependency and to correct a typographical error, and not for reasons of patentability. New Claims 17-59 were added.

Objection to Claim 16

Claim 16 was objected to because the term "pivotably" should be spelled correctly "pivotally." Applicants have amended Claim 16 accordingly.

Rejection of Claims under 35 U.S.C. 112, second paragraph.

Claims 1-16 were rejected under 35 U.S.C., second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that Claim 1 and its dependent claims are rendered vague and indefinite because the claim fails to recite essential steps. While Applicants respectfully disagree that the original claims "omit matter disclosed to be essential to the invention as described in the specification," as required by M.P.E.P. § 2172.01, nevertheless, Applicants have amended Claim 1 to overcome the objection.

Claim 10 was rejected because "the heated fluid" in lines 1-2 lack sufficient antecedent basis. Claim 10 has been amended to correct its dependency which now provides the proper antecedent basis.

The Examiner further points out that in Claim 15, line 2, "the inflation cycle" lacks sufficient antecedent basis. Claim 15 has been amended to correct its dependency which now provides the proper antecedent basis for the term.

The Examiner finally notes that Claims 10, 12, 13 and 15 are confusing because it is unclear if the dependency is intended as recited. Applicants would like to thank the Examiner for this observation. Claims 10, and 12-15 have been amended to correct their dependency.

Rejections under 35 U.S.C. 103(a)

Claims 1-4, 6-8 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Love et al. Applicants respectfully submit that claims 1-4, 6-8 and 11 define over Love et al. and are in condition for allowance.

Specifically, Love et al. discloses a method for obtaining cellular, chemical, and other materials from breast ducts comprising invasively accessing a single milk duct, infusing the duct with a washing fluid, and collecting the washing fluid along with marker materials from within the duct. *See* Abstract. Even more specifically, each ductal orifice is identified and labeled, Col. 6, lines 30-32. Typically, a guide wire is inserted into a ductal orifice a distance between .25 cm to 2.5 cm, Col. 7, lines 34-36. A catheter is then introduced into the ductal network over the guidewire, *Id.* at lines 38-43. In many of the disclosed experiments, a metal dilator was used to dilate the ductal orifice to approximately 0.7 to 1.0 mm to facilitate insertion of the catheter. Col. 12, lines 13-15.

Once the catheter has been inserted into the ductal network, a washing fluid is introduced through the catheter to substantially fill the ductal volume, Col. 7, lines 49-52. As the washing fluid fills the ductal network, "the fluid will flow outwardly in response to the positive pressure created by the inflow of washing fluid." Col. 8, lines 5-7. The breast can then be subjected to external pressure comprising massaging and/or squeezing to force the washing fluid to flow through a second lumen in the catheter. *Id.* at 20 et seq. "Massaging and squeezing actions applied to the breast are designed to mix the fluid and ductal contents together in the duct (by massaging) and to coax the fluid and other ductal contents to the ductal orifice (by squeezing)." *Id.* at 58-62.

In contrast to the invasive catheterization method and teaching of Love, Claim 1 recites, *inter alia*, "providing an intraductal fluid sampling device having an adjustable support, at least one inflatable bladder carried by the support and a patient interface surface carried by the bladder; adjusting the support to correspond with the approximate size of a breast to be tested; placing the interface in contact with the breast; inflating the bladder to provide compression to the breast; and noninvasively obtaining the intraductal fluid sample." Nowhere does Love teach or suggest such a method. Accordingly, Claim 1 would not have been obvious in view of Love et al. and Applicants respectfully request allowance of Claim 1.

Applicants respectfully submit that the Examiner's assertion that "it would have been well within the purview of one of ordinary skill in the art to perfect adjustments, contacting steps and inflating steps as a matter of routine experimentation" misapplies the statutory standard. A *prima facie* case of obviousness under §103 can only be established if the primary reference and

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one or more secondary references disclosed every element in the claim as well as a motivation to combine the elements in the manner claimed.

As the Examiner acknowledged, "Love does not teach the adjusting, contacting and inflating steps as claimed". Applicants respectfully submit that the various suggestions of Love et al., en route to its highly invasive transductal catheterization method, are simply insufficient to suggest Applicants' claimed invention in which a device is provided and used in a specific sequence of method steps. For example, although the passages cited by the Examiner disclose vague references to various mechanical pressure sources, nowhere in the cited passages does Love disclose a structure or the use of a structure which is capable of a first rough adjustment to approximate the size of a breast prior to inflating a bladder to provide compression. Moreover, the invasive catheterization of Love et al. teaches away from Applicants' method for noninvasively obtaining the intraductal fluid sample.

In addition, the claims that depend from Claim 1 each recite a unique combination of features not taught or suggested by Love et al. Accordingly, Applicants submit that dependent Claims 2-16 are in condition for allowance and requests the same.

New Claims

New Claims 17-59 have been added. Applicants submit that Claims 17-59 each define over the prior art of record and is in condition for allowance. New independent Claim 17 corresponds to original Claim 5. New independent Claim 30 corresponds to original Claim 9. New independent Claim 45 corresponds to original Claim 16.

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CONCLUSION

Based on the above, Applicants submit that all the pending claims are in condition for allowance and respectfully requests the same. Applicants have endeavored to respond to each of the issues presented by the Examiner. However, if there remain any issues that could be resolved during a telephone conference, then Applicants' representative invites the Examiner to initiate the same with the undersigned at the number shown below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 28 Apr 2003

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